

NOT FOR PUBLICATION

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

THE MEDICINES COMPANY,

Plaintiff,

v.

EAGLE PHARMACEUTICALS, INC. et al.:

Defendants.

:
:
:
:
:
:
:
:
:
:
:
:
:
:

Civil Action No. 16-569 (SRC)

OPINION & ORDER

CHESLER, U.S.D.J.

This matter comes before this Court on the motion to dismiss the Amended Complaint for failure to state a valid claim for relief, pursuant to Federal Rule of Civil Procedure 12(b)(6), by Defendants Eagle Pharmaceuticals, Inc. (“Eagle”), Scidose LLC, and Therdose Pharma PVT. LTD. (collectively, “Defendants”). For the reasons stated below, the motion will be denied.

This case arises from a dispute between pharmaceutical companies related to a medication, bivalirudin. In brief, the Amended Complaint alleges that the parties entered into the “Development Agreement” with the goal of developing a ready-to-use (“RTU”) formulation of Plaintiff’s bivalirudin product, Angiomax®. Two patents issued from the development program, U.S. Patent Nos. 7,713,928 and 7,803,762 (the “Patents at issue.”) The Amended Complaint alleges that Defendants terminated the Development Agreement and misappropriated the program’s intellectual property; Eagle filed a patent application for a RTU bivalirudin product. The Amended Complaint asserts seventeen claims: 1 and 2) patent infringement; 3) declaratory judgment of patent ownership; 4) breach of contract; 5) conversion; 6) misappropriation of intellectual property; 7) unjust enrichment; 8) constructive trust; 9) federal

trademark infringement; 10) false designation of origin and unfair competition under the Lanham Act; 11) common law unfair competition; 12) unfair competition under New Jersey law; 13) common law trademark infringement; 14) common law unfair and deceptive acts; 15) federal dilution; 16) New Jersey state law dilution and injury to business reputation; and 17) tortious interference with contract and prospective economic advantage.

Defendants moved to dismiss every claim in the Amended Complaint. Subsequently, the parties stipulated to the dismissal of Counts 9, 10, and 12 through 16, as well as the withdrawal of one allegation from Count 11. (Docket Entry No. 80.) Therefore, as to Counts 9, 10, and 12 through 16, the motion to dismiss will be denied as moot.

Defendants' motion to dismiss must be denied in largest part because it relies on factual matters extrinsic to the Amended Complaint. As a matter of black-letter law in the Third Circuit, "a district court ruling on a motion to dismiss may not consider matters extraneous to the pleadings." In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1426 (3d Cir. 1997). On a motion to dismiss, the Court "must accept all factual allegations in the complaint as true, construe the complaint in the light favorable to the plaintiff, and ultimately determine whether plaintiff may be entitled to relief under any reasonable reading of the complaint." Mayer v. Belichick, 605 F.3d 223, 229 (3d Cir. 2010). A movant cannot prevail on a motion to dismiss by asserting that the true facts are not as alleged in the Complaint.

Defendants move to dismiss the claims for infringement of the two Patents at issue, Counts 1 and 2, on two grounds: 1) 35 U.S.C. § 271(e)(2) applies only to patents listed in the Orange Book, and these are not; and 2) a joint owner of a patent cannot infringe it.

As to the Orange Book argument, the Amended Complaint alleges that Eagle has submitted an NDA under section 505(b)(2) of the FDCA, seeking approval for a bivalirudin

product. The relevant statute, 35 U.S.C. § 271(e)(2), states:

It shall be an act of infringement to submit--

(A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(j)] or described in section 505(b)(2) of such Act [21 USCS § 355(b)(2)] for a drug claimed in a patent or the use of which is claimed in a patent . . .

Defendants argue that the Amended Complaint does not allege sufficient facts to give this Court subject matter jurisdiction under 35 U.S.C. § 271(e)(2). This does not appear to be correct. The Amended Complaint alleges that Plaintiff co-owns two patents and that Eagle submitted an NDA under section 505(b)(2) for a drug claimed in those patents. Section 271(e)(2)(A) does not require more. This is sufficient to give this Court subject matter jurisdiction for the claims of patent infringement.

Defendants quote out of context the only Federal Circuit decision cited, AstraZeneca Pharms. LP v. Apotex Corp., 669 F.3d 1370, 1377 (Fed. Cir. 2012), which, contrary to Defendants' assertions, holds: "the requirements for jurisdiction in the district courts are met once a patent owner alleges that another's filing of an ANDA infringes its patent under § 271(e)(2), and this threshold jurisdictional determination does not depend on the ultimate merits of the claims." The Amended Complaint meets the jurisdictional requirements of AstraZeneca.¹

Defendants next argue that the patent infringement claims are invalid because a joint owner of a patent cannot infringe it. In opposition, Plaintiff argues that it is an exclusive licensee of the jointly owned patents under the Development Agreement, and that an exclusive

¹ Defendants also cite two district court cases, Eisai Co. v. Mut. Pharm. Co., No. CIV.A. 06-3613(HAA), 2007 WL 4556958, at *12 (D.N.J. Dec. 20, 2007) and Novo Nordisk Inc. v. Mylan Pharm. Inc., No. CIV A 09-2445 FLW, 2010 WL 1372437, at *10 (D.N.J. Mar. 31, 2010). These decisions were issued prior to AstraZeneca, and appear to run contrary to its guidance. Defendants have not shown that the Federal Circuit has agreed to "read a Paragraph IV requirement into § 271(e)(2)." Eisai, 2007 WL 4556958 at *12.

licensee may sue a patentee/infringer, citing Textile Prods. v. Mead Corp., 134 F.3d 1481, 1484 (Fed. Cir. 1998). In reply, Defendants appear to concede this point, but argue that the exclusive license did not survive the termination of the Development Agreement. This is both extraneous to the Amended Complaint and a legal conclusion. The Amended Complaint alleges that Eagle terminated the Development Agreement and that Plaintiff remains the exclusive licensee of the patents. At this juncture, this Court accepts these assertions as true and leaves their proof to summary judgment or trial. As to Counts 1 and 2, the motion to dismiss will be denied.

Defendants contend that the claims based on contractual rights, Counts 3 through 8, fail to state any valid claim for relief on two grounds: 1) the Amended Complaint fails to plead due performance; and 2) collateral estoppel, due to an arbitration award. Having asserted the first point, Defendants then admit that the Amended Complaint does, in fact, plead due performance, but contends that the allegation is false. As already explained, on a motion to dismiss, the well-pleaded factual allegations are taken as true. Arguments contesting the facts of performance and breach may succeed on summary judgment, but not now. Similarly, the alleged arbitration award is entirely extraneous to the Amended Complaint and will not be considered on this motion.

Defendants also argue that Counts 5 through 8, for conversion, misappropriation, unjust enrichment and constructive trust, are duplicative of the claim for breach of contract. In opposition, Plaintiff points out correctly that Federal Rule of Civil Procedure 8(d)(2) allows pleading in the alternative. These claims are alternative to the contract claims; they do not duplicate them.

As to Counts 3 through 8, the motion to dismiss will be denied.

Defendants originally moved to dismiss several claims, including the unfair competition

claims, Counts 10 and 11, with an argument targeting the trademark infringement elements of these claims. The parties subsequently stipulated to the dismissal of Counts 9, 10, and 12 through 16, as well as the withdrawal of one allegation of trademark infringement from Count 11. Having carved out and dismissed the trademark infringement issues, Defendants' argument for dismissal of Count 11 no longer applies, and the motion to dismiss Count 11 will be denied.

Lastly, Defendants move to dismiss Count 17, the tortious interference claim, with the argument that the allegation about the terms of the supply agreement, paragraph 100 of the Amended Complaint, is false. As discussed, at this juncture, the well-pleaded allegations in the Amended Complaint are taken as true, and the motion to dismiss on this point will be denied.

For these reasons,

IT IS on this 17th day of August, 2016

ORDERED that Defendants' motion to dismiss the Amended Complaint (Docket Entry No. 47) is **DENIED**.

s/ Stanley R. Chesler
STANLEY R. CHESLER, U.S.D.J.